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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 11/00 — A1

(11) International Publication Number: WO 96/38109

(43) International Publication Date: 5 December 1996 (05.12.96)

(21) International Application Number: PCT/US96/08190

(22) International Filing Date: 30 May 1996 (30.05.96)

(30) Priority Data:
08/458,497 2 June 1995 (02.06.95) US

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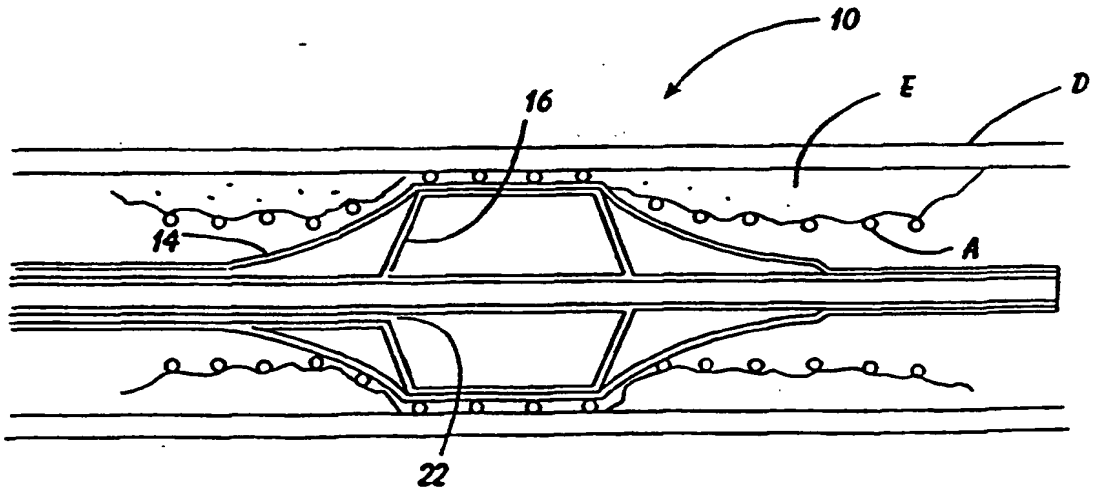
(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: DUAL BALLOON STENT DELIVERY CATHETER



(57) Abstract

A stent delivery apparatus (10) is disclosed, having an inner balloon (16) and an outer balloon (14) mounted near the distal end of a catheter (12). The outer balloon is a durable material such as polyethylene having a relatively thick wall to resist punctures by the stent (A) when the stent is crimped over the balloon. The outer balloon is expanded to a nominal diameter to expand the stent in place at the selected location in the lesion. The inner balloon is a high pressure material such as polyethylene terephthalate having a relatively thin wall to allow the balloon to be wrapped to a very low profile. The inner balloon is expanded to a nominal diameter to anchor the stent in place in the lesion, but will not stretch beyond its nominal diameter if further pressurized. The nominal expanded diameter of the inner ballon is greater than that of the outer balloon.

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DUAL BALLOON STENT DELIVERY CATHETER

FIELD OF INVENTION

This invention is in the field of catheters used to deliver a stent to a stenotic segment within an artery. Specifically, this invention is in a field which involves the use of a balloon on the catheter to expand the stent into place in the lesion.

BACKGROUND OF THE INVENTION

One method for revascularization of a stenotic segment within an artery is to place a stent across the lesion and expand the stent into place to maintain the arterial lumen at a desired diameter. This method typically involves making an incision in the groin to obtain access into the femoral artery. A guiding catheter is then introduced through the incision and into the artery and advanced over a guidewire to the stenotic segment.

To prepare for a stent placement operation, a stent is selected and mounted on an expandable placement balloon on a delivery catheter. This initial mounting is done with the placement balloon in the deflated condition. Often, the stent is slightly crimped, to maintain the stent in position on the placement balloon during introduction of the delivery catheter into the arterial system. The placement balloon, onto which the stent is placed and crimped, must be made of relatively tough material, to resist possible puncture during the crimping process. Further, the placement balloon material should be relatively thick, for the same reason. Polyethylene (PE) has been found to be a satisfactory material for placement balloons.

To perform the stent placement operation, the placement balloon, with the stent installed thereon, is advanced through the arterial system, over the guidewire, to the stenotic segment. The progress of the placement balloon and the stent through the vascular system is tracked radiographically, by monitoring the position of a

radiopaque marker in the vicinity of the balloon. During this process, radiographic dye must be routinely injected into the vascular system for contrast purposes. The amount of dye injected, however, must be minimized since the dye can be detrimental to several of the patient's organs.

When the stent has been placed as desired at the selected location within the stenotic segment, the placement balloon is inflated to expand the stent to a nominal expanded diameter. Inflation to the nominal expanded diameter is achieved by injection of a saline solution into the interior of the balloon, through a lumen in the delivery catheter. This nominal diameter is sufficiently large to at least temporarily hold the stent in place by contact between the stent and the stenotic material in the lesion.

To permanently place the stent, expansion of the stent beyond the initial placement expansion is normally required. This additional expansion is necessary in order to sufficiently embed the stent into the stenosis to permanently hold the stent in place, and to create a minimal lumenal diameter in the artery. Once the stent has been initially placed, however, several factors combine to prevent, or at least render more difficult, further expansion of the stent with the placement balloon. As mentioned above, the material of the placement balloon is a pliable but tough material, such as polyethylene. One limitation of polyethylene is its low burst pressure. Such a material is typically a distensible material which is capable of further expansion beyond the nominal expanded diameter. Consequently, if the typical placement balloon is further pressurized, because of the stretchability of the balloon material, the balloon tends to expand through the open ends of the stent. This "dog boning" tendency seriously reduces the ability of the placement balloon to cause further expansion of the stent, because of the possibility of damage to the artery at the proximal and

distal ends of the stent. An adverse consequence of this is that the actual diameter of the overexpanded stent becomes difficult to predict. Further, different stents possess different recoil characteristics, and different arterial wall thicknesses respond differently to stent overexpansion.

When the uncertainty of the stretchability characteristic of the placement balloon material and the low burst pressure are combined with the variables of differing stent recoil characteristics and differing arterial wall thicknesses, it is difficult for the physician to accurately expand the stent in a controlled fashion with the placement balloon, beyond the first nominal expanded diameter. For this reason, after expansion of the stent to the first nominal expanded diameter, the placement balloon is typically deflated and withdrawn from the stent, leaving the stent in the lesion. At this juncture, the stent is held in place only by contact with the stenotic material. So, as the delivery catheter and the placement balloon are withdrawn from the stent, it is necessary to use extreme caution to prevent dislodging the stent.

Once the delivery catheter and its placement balloon are completely withdrawn from the vascular system, a second catheter is then introduced into the artery, over the guidewire. This second catheter is fitted with a different type of balloon, which can be referred to as an anchoring balloon. The anchoring balloon is designed to be expanded to a second nominal diameter by application of a second nominal pressure. The second nominal diameter is larger than the first nominal diameter, to facilitate embedment of the stent firmly into the stenotic material. After the stent has been further expanded to the second nominal diameter by the anchoring balloon, thereby anchoring the stent in place, the balloon is deflated and withdrawn, along with the second catheter.

The anchoring balloon is made from a material which will not appreciably expand beyond the second nominal diameter, even if increased inflation pressure is applied. Further, the material of the anchoring balloon need not be as puncture resistant as the placement balloon, since the stent is never crimped onto the anchoring balloon. Therefore, the material does not need to be as tough or as thick. The material needs to withstand very high inflation pressures. A material which has been found useful for the anchoring balloon is polyethylene terephthalate (PET).

The artery in which the stenotic segment is located is often tapered to a smaller diameter as it extends distally from the heart. If a cylindrical stent is simply expanded to a second nominal diameter as described above, it will substantially retain its cylindrical shape. If the artery is appreciably tapered, the stent will likely be sufficiently embedded at its distal end, but it may be less securely embedded, or even free, at its proximal end. This can cause the proximal end of the stent to project into the arterial lumen, which can allow snagging of the stent, promote thrombosis, or impair blood flow.

In order to prevent the proximal end of the stent from projecting into the arterial lumen, and to strengthen the embedding of the stent into the artery, the proximal end of the stent is often further expanded. This causes the stent to assume a tapered shape, more closely approximating the shape of the artery. This is typically accomplished by introducing a third catheter into the artery. The third catheter has a tapering balloon mounted thereon. Alternatively, the second and third catheters may be combined. The tapering balloon is typically shorter in length than the placement balloon or the anchoring balloon. The tapering balloon is placed within the proximal portion of the stent and expanded to a third nominal diameter which is larger than the second nominal diameter. This causes the proximal end of the stent to have a larger diameter

than the distal end thereof, resulting in an essentially tapered shape.

Since expansion of the proximal portion of the stent with the tapering balloon will embed the proximal end of the stent in the stenotic material, a relatively high pressure is used to achieve the third nominal diameter. This calls for the tapering balloon to be made of a material which, like the anchoring balloon, will not appreciably expand beyond the nominal expanded diameter of the balloon, even if the expansion pressure is increased. The tapering balloon is often made of PET.

It can be seen that the typical known procedure for delivery, anchoring, and tapering of a stent requires introduction and removal of at least two and maybe three separate delivery catheters into the artery. This causes increased trauma to arterial tissues, promotes thrombosis, and requires repeated dye injections. Introduction of the second and third delivery catheters into the stent for anchoring and tapering purposes can also dislodge the stent from the stenosis. A dislodged stent must be retrieved by further procedures, sometimes even major surgery. Furthermore, the anchoring or tapering balloon can snag on the stent, puncturing the balloon. A punctured balloon could result in creation of an embolism, or at the very least, require replacement of the catheter.

An object of the present invention is to provide a method and apparatus for delivery, anchoring, and tapering of a stent without repeated withdrawals and introductions of catheters. A further object of the present invention is to provide a method and apparatus for delivery, anchoring, and tapering of a stent, which uses a single catheter. A still further object of the present invention is to provide a method and apparatus for delivery, anchoring, and tapering of a stent, which provides a relatively stretchable balloon for placement of the stent and a relatively non-stretchable balloon for expanding and

tapering the stent, using a single catheter. A yet further object of the present invention is to provide a method and apparatus for delivery, anchoring, and tapering of a stent, which is easy and economical to use.

SUMMARY OF THE INVENTION

A stent delivery apparatus according to the present invention has an inner balloon and an outer balloon mounted near the distal end of a catheter. An outer balloon has a length which is approximately equal to the length of the stent to be delivered. An inner balloon is mounted to the catheter, at a location inside the outer balloon. This inner balloon has a shorter length than the outer balloon.

The catheter has three lumens. One lumen passes the full length of the catheter from the proximal end to the distal end. This lumen is used for the passage of the catheter over a guidewire for guiding the delivery catheter to a stenosis in the vascular system of the patient. A second lumen passes from the proximal end of the catheter to the inside of the outer balloon. This lumen is used for inflating the outer balloon. The third lumen passes from the proximal end of the catheter to the inside of the inner balloon and is used for inflating the inner balloon.

The outer balloon is made of a relatively durable material such as polyethylene (PE) having a relatively thick wall to resist punctures by the stent when the stent is crimped over the balloon. The polyethylene of the outer balloon is also distensible, or stretchable. Thus, pressurization of the outer balloon to a nominal pressure expands the balloon to a first nominal expanded diameter. When the outer balloon is inflated and deflated, it is soft and tends to rewrap more readily than the stiffer high strength balloons. When the stent is placed on the outer balloon, the stent is secured in place on the balloon by being crimped onto the balloon. The expanded diameter of the outer balloon is selected to expand the stent to a

proper diameter for initial placement of the stent in the artery.

The inner balloon is a high strength material such as polyethylene terephthalate (PET) having a relatively thin wall to allow the balloon to fold to a very low profile when initially wrapped. When the inner balloon expands, the expansion is achieved largely through unfolding of the balloon material, with very little stretching. When pressurized, the inner balloon will expand to a second nominal diameter, but essentially no further. An inner balloon has a selected second nominal expanded diameter to properly embed the stent into the stenosis. Increased internal pressure can be used to achieve the second nominal expanded diameter against external resistance. The inner balloon can be located near the center of the outer balloon, or it can be located near the proximal end of the outer balloon.

After placement of the stent over the outer balloon, the delivery catheter, with the stent installed, is introduced into the patient's vascular system. Through radiography, the stent is placed in the stenosis. The outer balloon is pressurized and expanded to a first nominal diameter to expand the stent in place at the selected location in the lesion to initially embed the stent. The outer balloon is then deflated.

The inner balloon is then pressurized and expanded to a second nominal diameter to embed the stent into the stenotic material and anchor the stent in place in the lesion. Increased pressure can be used to properly embed the stent in the stenotic material. The inner balloon will not stretch more than a minimal amount beyond its nominal expanded diameter, even if further pressurized beyond the nominal expansion pressure. The nominal expanded diameter of the inner balloon, referred to here as the second nominal diameter, is greater than the nominal expanded

diameter of the outer balloon, referred to here as the first nominal expanded diameter.

If the artery is essentially untapered, the delivery catheter used can have the inner balloon located essentially at the center of the stent. In such a case, expansion of the inner balloon to the second nominal diameter will concentrate the embedding force in the center of the stent, and the stent will substantially retain its cylindrical shape. Conversely, if the artery is tapered in the area of the lesion, the delivery catheter inner balloon should be located in the proximal portion of the stent. Expansion of the inner balloon in such an embodiment will concentrate the force in the proximal portion of the stent, and the stent will take on a tapered shape to match the artery.

The novel features of this invention, as well as the invention itself, both as to its structure and its operation, will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a stent installed on a delivery catheter, prior to expansion;

Figure 2 is a perspective view of the prior art stent and delivery catheter shown in Figure 1, after expansion;

Figure 3 is a longitudinal section view of the delivery apparatus of the present invention, with the outer balloon inflated to place the stent against the stenosis;

Figure 4 is a longitudinal section view of the apparatus of Figure 3, with the outer balloon deflated and the inner balloon inflated to embed the stent into the stenosis;

Figure 5 is a longitudinal section view of the stent anchored in the stenosis, after withdrawal of the apparatus of Figure 3;

Figure 6 is a longitudinal section view of an alternate embodiment of the delivery apparatus of the present invention, for use in a tapered artery, with the outer balloon inflated to place the stent against the stenosis;

Figure 7 is a longitudinal section view of the apparatus of Figure 6, with the outer balloon deflated and the inner balloon inflated to embed the stent into the stenosis;

Figure 8 is a longitudinal section view of the stent anchored in the tapered stenosis, after withdrawal of the apparatus of Figure 6;

Figure 9 is a transverse section view of the triple lumen catheter shown in Figure 3, taken at line 9-9; and

Figures 10 through 12 are transverse section views of alternate embodiments of the triple lumen catheter.

DESCRIPTION OF PREFERRED EMBODIMENTS

Figure 1 illustrates a typical cylindrical stent A installed on a typical placement balloon B, with the placement balloon B mounted on a typical delivery catheter C. The placement balloon B is wrapped or folded to its smallest diameter, and the stent A is shown in the unexpanded state. The stent A is crimped onto the placement balloon B, to hold the stent A on the balloon B during introduction of the catheter C into the patient's vascular system.

Figure 2 shows the stent A, the placement balloon B, and the catheter C of Figure 1, with the balloon B inflated and the stent A expanded to a first nominal diameter. This figure illustrates that the stent A can be an expandable lattice of longitudinal members. The stent A could also be any other known style of expandable structure. It is also

possible that the stent A could be secured in place on the balloon B by some means other than crimping.

In the case of the typical known delivery catheter system, after inflation of the placement balloon B as shown in Figure 2, the balloon B would be deflated and withdrawn from the stent A, leaving the stent A temporarily in place in the artery. A second catheter (not shown) would then be introduced through the artery to place an anchoring balloon within the stent A, and the anchoring balloon would be inflated to expand the stent A to a second nominal expanded diameter. This would embed the stent A into the stenosis. Finally, if the artery were tapered, a third catheter (not shown) would be introduced, and a tapering balloon would be inflated in the proximal portion of the stent A to taper the stent A and embed the proximal end of the stent into the stenosis.

As shown in Figure 3, the apparatus of the present invention 10 includes a triple lumen delivery catheter 12. An outer balloon 14 and an inner balloon 16 are mounted on the catheter 12 adjacent the distal end of the catheter 12. The catheter 12 can have a radiopaque marker placed centrally within the outer balloon 14. The inner balloon 16 is shown deflated. The inner balloon 16 is shorter than the outer balloon 14, and in this embodiment it is located approximately in the center of the outer balloon 14. The artery D depicted in Figure 3 is essentially untapered. Deposition of stenotic material E on the arterial wall is evenly distributed around the arterial lumen. A guidewire 18 passes through the entire length of the catheter 12 in a central lumen therein, extending from the proximal and distal ends thereof.

The outer balloon 14 is shown inflated to its nominal expanded diameter, thereby expanding the stent A to a first nominal diameter. The outer balloon 14 is made of a durable material such as polyethylene (PE), and it has a relatively thick wall to prevent damage by crimping of the

stent A. Expansion of the outer balloon 14 to the first nominal diameter is achieved by pressurizing the outer balloon 14 to a first nominal pressure via a first inflation port 20. The expanded stent A is in contact with the stenotic material E, but it is not securely embedded into the stenotic material E.

Figure 4 shows the outer balloon 14 depressurized and deflated. The inner balloon 16, however, is pressurized to a second nominal pressure via a second inflation port 22. The inner balloon 16 is made of a high strength material such as polyethylene terephthalate (PET), and it has a relatively thin wall to allow the inner balloon 16 to fold to a very low profile. The inner balloon 16 has expanded to a second nominal diameter which is greater than the first nominal diameter. Expansion of the inner balloon 16 to the second nominal diameter has expanded at least a portion of the stent A to the second nominal diameter to embed the stent A into the stenotic material E. Since the inner balloon 16 is located near the longitudinal center of the stent A, embedment of the stent A into the stenotic material E is concentrated near the center of the stent A. The inner balloon 16 can be repositioned within the stent A as needed using a radiopaque marker and radiographic dye, and inflated to expand the stent A along its length to achieve the configuration shown in Figure 5. Ideally, if the high pressure balloon is inflated past its nominal inflation range, the combined balloon strengths will allow for a third diameter.

Figure 5 shows the stent A remaining in the stenosis after withdrawal of the delivery catheter 10. The stent A is partially embedded into the stenotic material E to hold the stent A securely in place. The configuration of the stent A is essentially cylindrical.

Figure 6 shows an alternate embodiment 10' of the present invention to be used in tapered arteries. Expansion of the outer balloon 14 to the first nominal

diameter places only the distal portion of the stent A in contact with the stenosis. The proximal portion of the stent A projects outwardly into the arterial lumen. Figure 7 shows the alternate embodiment of the delivery apparatus 10' after deflation of the outer balloon 14 and after expansion of the inner balloon 16 to the second nominal diameter. As can be seen, in this alternate embodiment, the inner balloon 16 is located within the proximal portion of the outer balloon 14. So, expansion of the inner balloon 16 expands the proximal portion of the stent A more than the distal portion of the stent A. This causes the stent A to assume a tapered shape approximating the shape of the artery D.

Figure 8 shows the stent A remaining in the tapered stenosis after withdrawal of the alternate embodiment of the delivery catheter 10'. The stent A is partially embedded into the stenotic material E to hold the stent A securely in place. The configuration of the stent A is tapered.

Figure 9 shows a transverse section view of one embodiment of the triple lumen delivery catheter 12. A first inflation lumen 24, in a semi-annular configuration, leads from the proximal end of the catheter 12 to the first inflation port 20. The first inflation lumen 24 is used to pressurize and inflate the outer balloon 14. A second inflation lumen 26, also in a semi-annular configuration, leads from the proximal end of the catheter 12 to the second inflation port 22. The second inflation lumen 26 is used to pressurize and inflate the inner balloon 16. A guidewire lumen 28 having a circular cross section, located between the first and second inflation lumens 24, 26, passes from the proximal end to the distal end of the catheter 12, to provide a passageway for the guidewire 18.

Figures 10, 11, and 12 show transverse section views of alternate embodiments of the triple lumen catheter 12', 12'', and 12'''. The first and second inflation lumens can

be various shapes, but the guidewire lumens should be circular to prevent pinching of the guidewire 18.

OPERATION

First, a large guidewire (not shown) is introduced into the patient's vascular system and advanced to the artery D. Then, a guiding catheter (not shown) as known in the art is introduced into the artery D over the guidewire 18. A stent A having the proper diameter for the artery D is selected. A delivery catheter 12 having an outer balloon 14 of proper diameter, and having an inner balloon 16 of proper diameter and placement, is selected. The stent A is placed on the outer balloon 14 and the stent A is crimped onto the outer balloon 14.

The delivery catheter 10 is introduced into the guiding catheter and advanced to the stenosis over the guidewire 18. Advancement of the stent is monitored radiographically. When the stent A is located as desired within the lesion, the outer balloon 14 is pressurized to a first nominal pressure and expanded to a first nominal expanded diameter. This causes the stent A to contact the stenotic material E sufficiently to hold the stent A in place temporarily. The outer balloon 14 is then depressurized and deflated. The inner balloon 16 is then pressurized to a second nominal pressure and expanded to a second nominal expanded diameter. This causes the stent A to be embedded securely into the stenotic material E. The inner balloon 16 is then depressurized and deflated. The apparatus 10 is then withdrawn.

While the particular DUAL BALLOON STENT DELIVERY CATHETER as herein shown and disclosed in detail is fully capable of obtaining the objects and providing the advantages herein before stated, it is to be understood that it is merely illustrative of the presently preferred embodiments of the invention and that no limitations are

intended to the details of construction or design herein shown other than as described in the appended claims.

I claim:

1. A stent delivery apparatus, comprising:

a tubular catheter, said catheter having a proximal end and a distal end;

an outer balloon mounted on said catheter adjacent said distal end, said outer balloon being inflatable to expand a stent to a first nominal diameter, said outer balloon being substantially stretchable beyond said first nominal diameter;

an inner balloon mounted on said catheter within said outer balloon, said inner balloon being inflatable to further expand the stent to a second nominal diameter, said inner balloon being substantially non-stretchable beyond said second nominal diameter, said second nominal diameter being greater than said first nominal diameter;

a guidewire lumen through said balloons;

a first inflation lumen through said catheter from said proximal end to said outer balloon; and

a second inflation lumen through said catheter from said proximal end to said inner balloon.

2. A stent delivery apparatus as recited in claim 1, wherein said outer balloon is constructed of a relatively distensible material of sufficient wall thickness to resist puncturing by the stent.

3. A stent delivery apparatus as recited in claim 2, wherein said relatively distensible material is a polymeric material.

4. A stent delivery apparatus as recited in claim 3, wherein said polymeric material is polyethylene.

5. A stent delivery apparatus as recited in claim 1, wherein said inner balloon is constructed of a non-
3 distensible material having a sufficiently thin wall to allow shaping of said inner balloon to a low profile.

6. A stent delivery apparatus as recited in claim 5, wherein said non-distensible material is polyethylene
3 terephthalate.

7. A stent delivery apparatus as recited in claim 1, wherein said outer balloon has a length selected to match
3 the length of the stent.

8. A stent delivery apparatus as recited in claim 1, wherein said inner balloon has a length substantially less
3 than the length of the stent.

9. A stent delivery apparatus as recited in claim 8, wherein:

3 said inner balloon is positioned within a proximal portion of said outer balloon; and

inflation of said inner balloon further expands
6 a proximal portion of the stent to taper the stent.

10. A stent delivery apparatus as recited in claim 1, further comprising a guidewire fixed inside said catheter.

11. A stent delivery apparatus, comprising:

a tubular catheter, said catheter having a proximal end and a distal end;

a polyethylene balloon mounted on said catheter adjacent said distal end, said polyethylene balloon being inflatable to expand a stent to a first nominal diameter;

a PET balloon mounted on said catheter within a proximal portion of said polyethylene balloon, said PET balloon being inflatable to further expand a proximal portion of the stent to a second nominal diameter to taper the stent;

a guidewire lumen through said catheter from said proximal end of said catheter to a distal end of said polyethylene balloon;

a first inflation lumen through said catheter from said proximal end to said polyethylene balloon; and

a second inflation lumen through said catheter from said proximal end to said PET balloon;

wherein said second nominal diameter is greater than said first nominal diameter.

12. A method for delivering a stent to a selected location in a blood vessel, said method comprising the steps of:

providing a stent;

providing a stent delivery apparatus having an outer balloon mounted on a catheter and an inner balloon mounted on said catheter within said outer balloon;

placing said stent over said outer balloon, with said balloons deflated;

introducing said apparatus and said stent through the blood vessel to locate said stent at said selected location;

inflating said outer balloon to expand said stent to a first diameter; and

inflating said inner balloon to expand said stent to a second diameter, said second diameter being greater than said first diameter.

13. A method for delivering a stent as recited in claim 12, said method further comprising the steps of:

providing a guidewire; and

introducing said guidewire through the blood vessel to said selected location for said stent;

wherein said step of introducing said apparatus through the blood vessel is performed by advancing a guidewire lumen of said catheter over said guidewire.

14. A method for delivering a stent as recited in claim 12, wherein said step of inflating said outer balloon is performed by pressurizing said outer balloon via a first inflation lumen in said catheter.

15. A method for delivering a stent as recited in claim 14, wherein said step of inflating said inner balloon is performed by pressurizing said inner balloon via a second inflation lumen in said catheter.

16. A method for delivering a stent as recited in claim 12, said method further comprising the step of crimping said stent over said outer balloon to hold said stent in place on said outer balloon.

17. A method for delivering a stent as recited in claim 12, said method further comprising the step of deflating said outer balloon prior to said step of inflating said inner balloon.

18. A method for delivering a stent as recited in claim 12, said method further comprising the steps of:

deflating said inner balloon; and

withdrawing said stent delivery apparatus from the blood vessel while leaving said stent in said selected location.

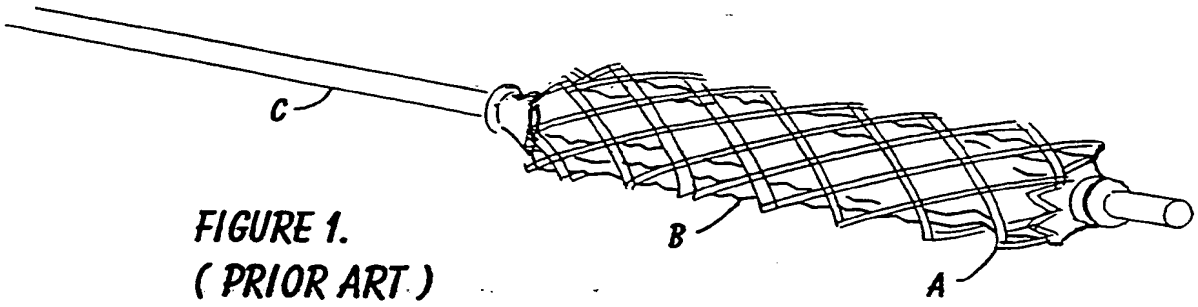

FIGURE 1.
(PRIOR ART)

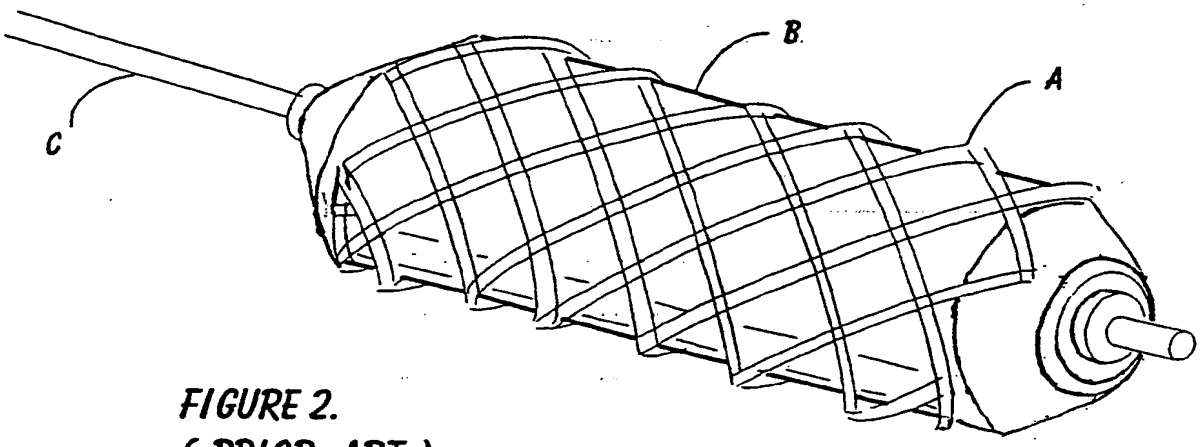

FIGURE 2.
(PRIOR ART)

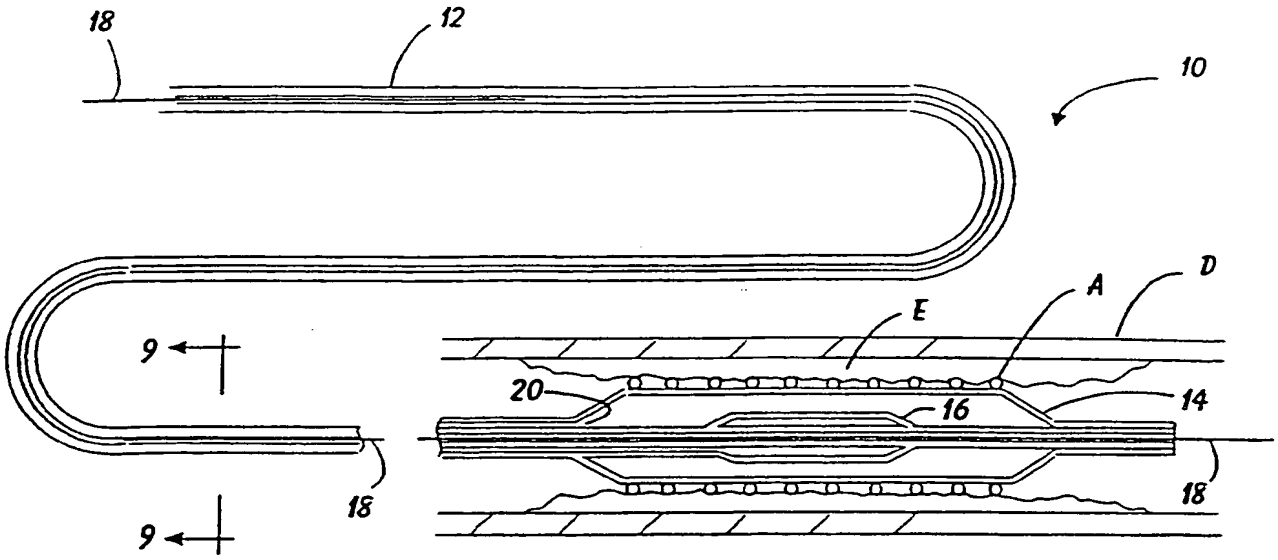

FIGURE 3.

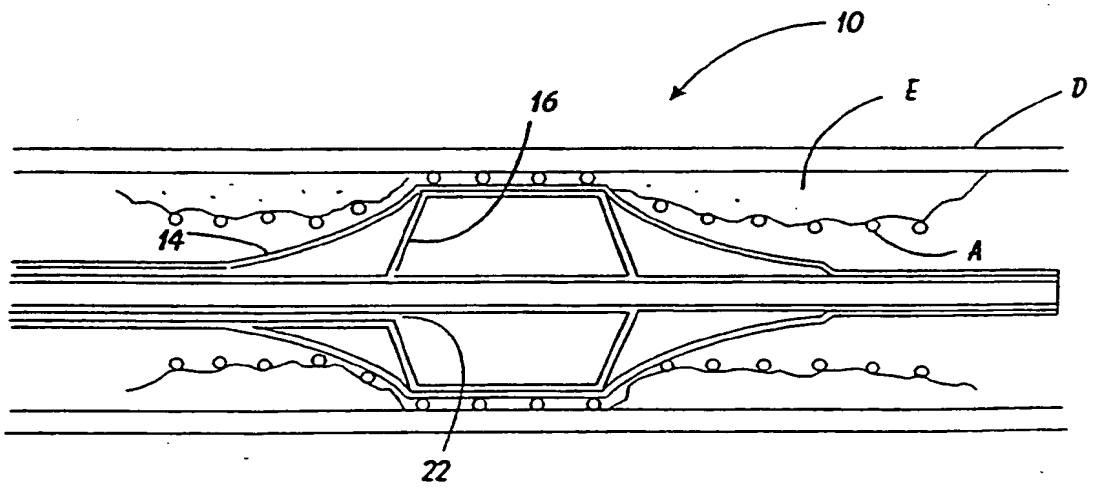

FIGURE 4.

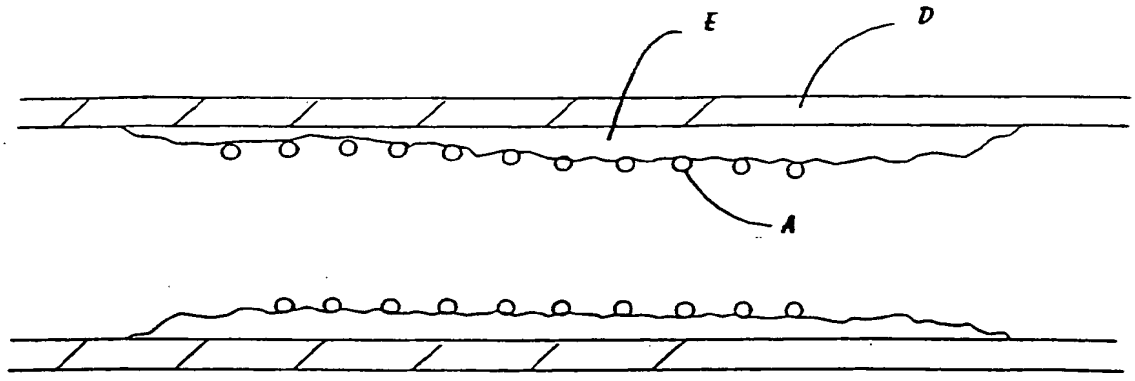

FIGURE 5.

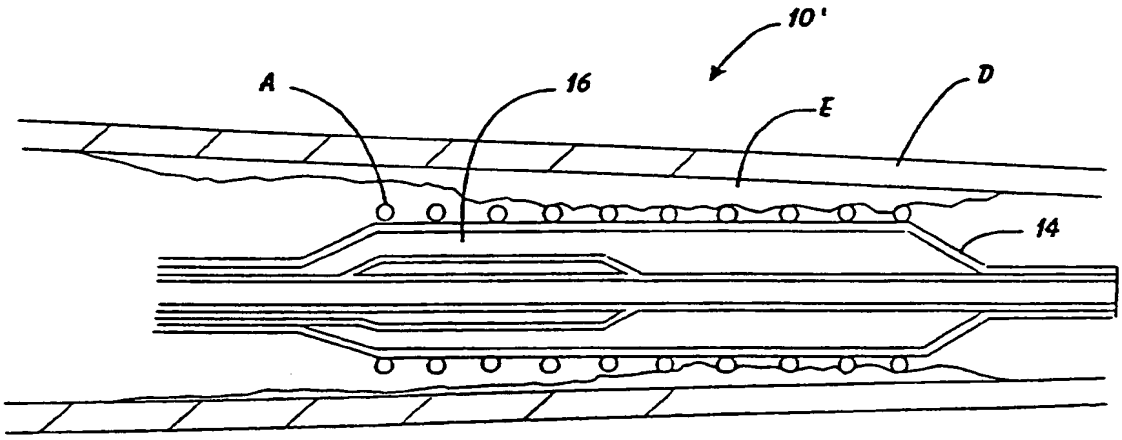

FIGURE 6.

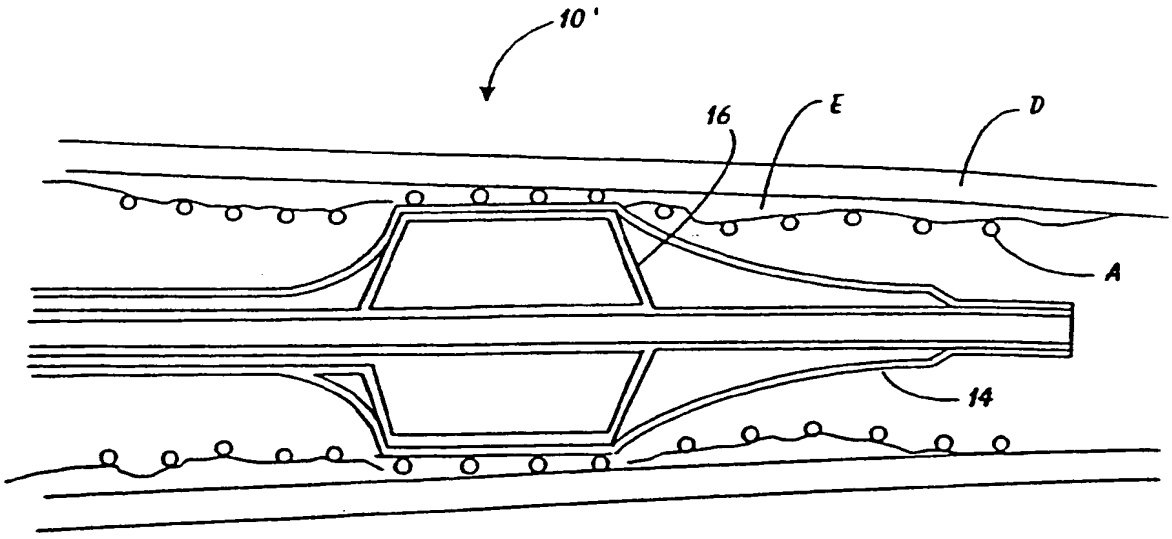

FIGURE 7.

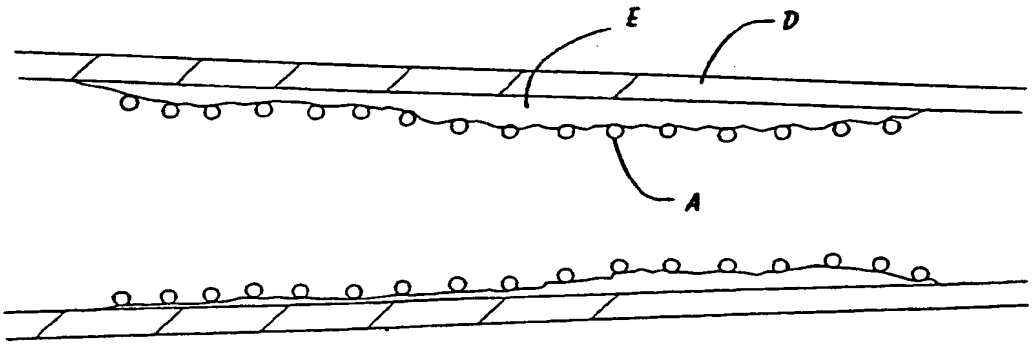

FIGURE 8.

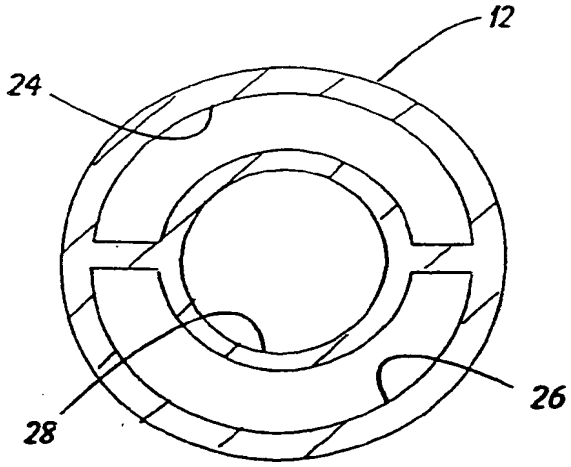

FIGURE 9.

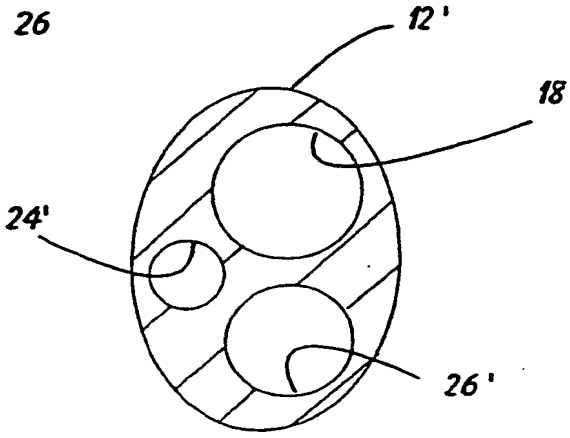

FIGURE 10.

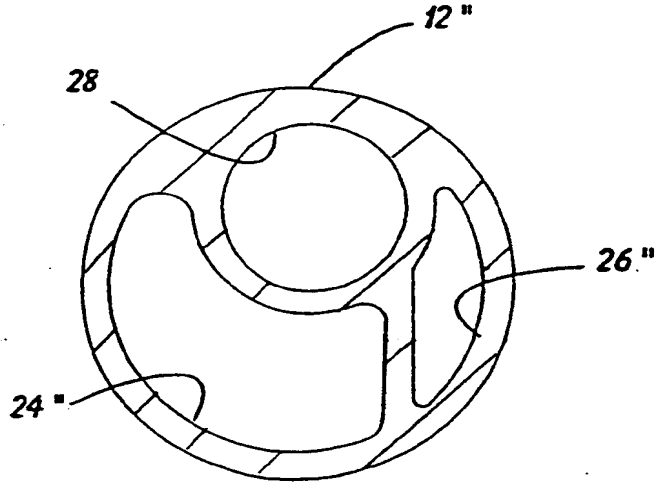

FIGURE 11.

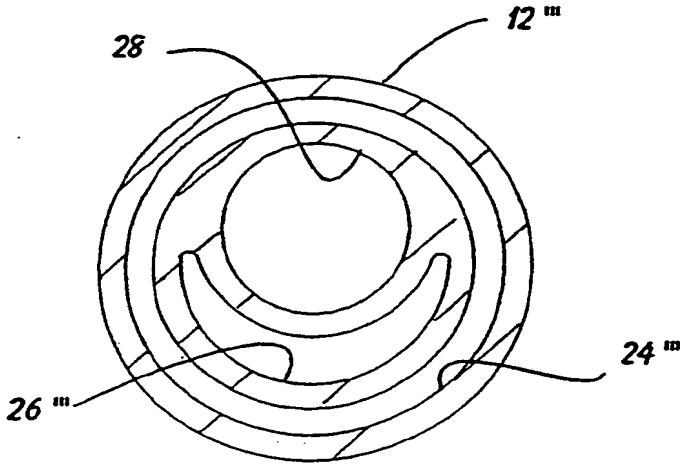

FIGURE 12.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/08190

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61F 11/00
US CL :606/108
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/108

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4744,366 (JANG) 17 May 1988, see Fig. 6.	1
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Y		2-18
Y, P	US, A, 5,505,699 (FORMAN ET AL.) 09 April 1996.	2-18

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 15 AUGUST 1996	Date of mailing of the international search report 27 SEP 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer BENJAMIN KOO Telephone No. (703) 308-2657

Form PCT/ISA/210 (second sheet)(July 1992)*